UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,355	07/31/2006	Colin G. Caro	DEHN 2 00009	6723

27885 7590 04/21/2009

Fay Sharpe LLP
1228 Euclid Avenue, 5th Floor
The Halle Building
Cleveland, OH 44115

EXAMINER	
TANNER, JOCELIN C	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
04/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,355	CARO ET AL.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12,13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12,13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/02/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the Amendment filed 2 April 2009. Claims 1, 3-10, 12, 13 and 15-23 are currently pending. The Examiner acknowledges the amendment to claim 12 and the cancelled claims 2, 11 and 14.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 April 2009 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 12-19, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713).

5. Regarding claim **12**, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line

and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration (column 5, lines 53-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

6. Regarding claim **13**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston et al. fails to disclose the value of 0.05 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held

that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

7. Regarding claim **14**, Houston et al. discloses a stent that is substantially free of ribs that would interfere within the flow lumen in its expanded condition (Fig. 5).

8. Regarding claim **15**, Houston et al. discloses Houston et al. discloses a stent (300) having an expanded configuration with a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 15° ([0010]).

9. Regarding claim **16**, Houston et al. discloses a stent having a circular cross-section (Fig. 5).

10. Regarding claim **17**, Houston et al. discloses a helical center line of the stent extending over part of the overall length of the stent (Fig. 5).

11. Regarding claim **18**, Houston et al. discloses a helical center line of the stent extending over substantially the entire length of the stent (Fig. 5).

12. Regarding claim **19**, Houston et al. discloses a helical center line following a substantially helical path about a curved axis (Fig. 5).

13. Regarding claim **21**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston fails to disclose the value of 0.1 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing

the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

14. Regarding claim **23**, Houston et al. discloses a stent having a helical portion that has the same number of turns in the expanded and collapsed conditions (Fig. 5).

15. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713), as applied to claim 12 above, and further in view of Igaki et al. (US Patent No. 5,733,327).

Regarding claim **20**, the combination of Houston et al. and Evans et al. discloses all of the limitations previously discussed except for a pharmaceutical coating.

Igaki et al teach coating a stent to provide locally limited and long-term dosage of drugs (column 2, line 51 and column 3, lines 19-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of the combination of Houston et al. and Evans et al., with the coating or drug induced fiber, as taught by Igaki et al., to provide locally limited and long-term dosage of drugs.

16. Claims 1, 3-6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713), as applied to claim 12 above, and further in view of Hogan (US Patent No. 6,569,191).

17. Regarding claim **1**, Houston et al. in view of Evans et al. discloses a stent (11) having a helix structure and formed of a synthetic material and having an outer wall that radially expands. The combination of Houston et al. and Evans et al. fails to disclose wall portions that have more of a resistance to extension than the helical portions.

Hogan teaches an expandable stent wherein rigid longitudinal strips (40) are attached to the helically wound threads that form the wall of the stent and exert an increased longitudinally constricting force (column 7, lines 1-12, Fig. 4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided longitudinal extension resistance to the stent of the combination of Houston et al. and Evans et al., as taught by Hogan, to increase radial expansion to obtain a desired final diameter.

18. Regarding claim **3**, Hogan teaches helical supplemental threads (30) of different material or thickness that increase the amount of stent forming material (column 6, lines 33-37, Fig. 2).

19. Regarding claim **4**, Houston et al. discloses a stent having curved or "bent" portions wherein the bent portions remain bent when expanded (Fig. 5).

20. Regarding claims **5 and 6**, Hogan teaches a self- expanding and balloon-expandable stent (column 8, lines 17-21).

21. Regarding claim **22**, Houston et al. discloses a stent (11) undergoing a turn of the helix wherein the stent has a helical configuration with at least one helical turn (Fig. 5).

22. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US

Patent No. 5,709,713), as applied to claim 12 above, and further in view of Inderbitzen et al. (US Patent No. 5,484,411).

23. Regarding claim **9**, the combination of Houston et al. and Evans et al. discloses a balloon expandable stent (column 3, lines 2-6, Evans et al.). However, the combination of Houston et al. and Evans et al. fails to disclose a balloon having an expandable wall that resists extension more helical portions of the balloon.

Inderbitzen et al. teaches an expandable balloon used in angioplasty procedures including a longitudinally extending spiral wall (38) extending from the distal to proximal end of the balloon, formed integrally with the exterior surface of the balloon and radially restricting the expansion of the balloon along the longitudinally extending spiral path (column 3, lines 45-53, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the balloon of the combination of Houston et al. and Evans et al., with a helical portion, as taught by Inderbitzen et al., to exhibit a low crossing profile and to avoid the need to rotate the balloon within a vessel to ensure dilation.

24. Regarding claim **10**, Inderbitzen et al. teaches a balloon having an exterior surface or expandable wall wherein the wall thickness is greater in sections include a spiral wall or "helical portion" (38) (Fig. 2).

Response to Arguments

25. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection wherein a new embodiment (Fig. 5) of

Houston et al. has been used to show a helical center line and to address the Applicant's arguments of an expandable and collapsible stent. Houston et al. appears to disclose an expandable stent as the stent is disclosed as being collapsible, but the prior art of Evans et al. expressly teaches an expandable stent and has been added to the rejection. The Applicant contends that the structure of Houston et al. in Figs. 4A and 5 is not a stent but external scaffolds. However, Houston et al. discloses that the device may be a stent formed of a mesh [0025] that is placed inside or outside a vessel to maintain and reinforce a flow guiding formation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
4/15/2009
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/20/09